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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,869

10/21/2005

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06/18/2009

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EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

06/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/553,869</p>	<p>Applicant(s) LORENTSEN ET AL.</p>	
	<p>Examiner SHERIDAN SWOPE</p>	<p>Art Unit 1652</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 June 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: 1, 4, 6, 8-11, 13-17, 40, 41, and 43-51.
Claim(s) rejected: 1, 4, 6, 8-11, 13-17, 40, 41 and 43-51.
Claim(s) withdrawn from consideration: 12 and 18-39.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652

Claims 7 and 42 have been cancelled. Claims 1, 4, 6, 8-41, and 43-51 are pending. Claims 12 and 18-39 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b). Claims 1, 4, 6, 8-11, 13-17, 40, 41, and 43-51 are under prosecution.

Continuation of 5. Applicant's reply has overcome the following rejection(s):

Objection to Claim 1 for missing an "and" at the end of line 14..

Objection to Claim 4, penultimate line, for "adjacent the cleavage site". Rejection of Claims 11 and 46 under 35 U.S.C. 112, second paragraph..

Rejection of Claims 8 and 43 under 35 U.S.C. 112, first paragraph/enablement, for the reasons explained in the prior actions, is maintained.

Regarding said rejection, applicants make the following arguments. Although Example 3 shows autolysis of a fusion protein comprising Granzyme B and a Granzyme B cleavage motif, the Example also shows that autoactivation of this peptide, without the addition of any previously activated Granzyme B, was not completed until after three days at 4 °C. (See specification, paragraph bridging pp. 43-44).

This argument is not found to be persuasive. Applicants have fail to show evidence that the rate of cleavage is faster with added Granzyme B, than autolysis, at the same temperature. For this reason and those explained in the prior actions, the rejection is maintained.

Rejection of Claims 8 and 43 under 35 U.S.C. 112, first paragraph/written description, for the reasons explained in the prior actions, is maintained.

Regarding said rejection, applicants make the following arguments. The specification describes that, while autoactivation of Granzyme B is contemplated, at least a "single molecule" of active Granzyme G can be added to a cleavage reaction. See p. 11, last paragraph. The addition of a "single molecule" of Granzyme B to the cleavage reaction provides support for claims 8 and 43.

This argument is not found to be persuasive. It is acknowledged that the specification asserts that a fusion protein comprising Granzyme B and a Granzyme B cleavage motif can be processed by added Granzyme B. However, Applicants have fail to show evidence that the rate of cleavage is faster with added Granzyme B, than autolysis, at the same temperature. For this reason and those explained in the prior actions, the rejection is maintained.

Rejection of Claims 1, 9-11, 16, 17, 40, 44-46, 50, and 51 under 35 U.S.C. 103(a) as being unpatentable over Azad et al, 1994 in view of Harris et al, 1998 and further in view of Casciola-Rosen et al, 1999, rejection of Claims 1, 4-6, 9-11, 16, 17, 40, 41, 44-46, 50, and 51 under 35 U.S.C. 103(a) as being unpatentable over the combination of Azad et al, Harris et al, and Casciola-Rosen et al in view of Boutin et al, 1997, and Claims 1, 9-11, 13-17, 40, and 44-51 under 35 U.S.C. 103(a) as being unpatentable over the combination of Azad et al, Harris et al, and Casciola-Rosen et al in view of Sigma Inc, 1998 or Pharmacia, Inc., for the reasons explained in the prior actions, are maintained.

Regarding said rejections, applicants make the following arguments.

(A) None of Azad et al, Harris et al, Casciola-Rosen et al, or Boutin et al teach production of a polypeptide in authentic form.

(A) Reply: The specification fails to limit the authentic form of the produced protein to having or not having an N-terminal Met. The specification merely states that "authentic form"... "refers to a polypeptide having the same primary amino acid sequence as that encoded by the native gene" [0024]. The skilled artisan would take said statement to encompass proteins both having and not having the encoded N-terminal Met. As explained in the prior action, Azad et al teaches an authentic form of nef27 (pg 65, parag 2), while Boutin et al teaches an authentic form of calcineurin (Table 3). For this reason and those explained in the prior actions, the rejection is maintained.